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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,979	12/08/2003	Tomoya Miyakawa	Q78853	2814
23373 7590 01/02/2008 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER ZHOU, SHUBO	
			ART UNIT 1631	PAPER NUMBER
			MAIL DATE 01/02/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/728,979

Applicant(s)

MIYAKAWA ET AL.

Examiner

Shubo (Joe) Zhou

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2007 and 04 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-19, 21-29, 34, 35, 38, 41-49, 51-59, 61 and 62 is/are pending in the application.
- 4a) Of the above claim(s) 4-5, 8, 14-15, 18, 24-25, 28, 34-35, 38, 44-45, 48, 54-55, and 58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6, 7, 9, 11-13, 16, 17, 19, 21-23, 26, 27, 29, 41-43, 46, 47, 49, 51-53, 56, 57, 59, 61 and 62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 4/18/07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Amendments and Sequence Rules Compliance

Applicant's amendments and request for reconsideration filed 2/12/07 and the sequence listing filed 6/4/07 are acknowledged. The amendments filed 2/12/07 are entered and the sequence listing including the paper copy and the computer readable form thereof and the statement under 37 CFR 1.821(f) filed 6/4/07 are accepted.

Claims 1-9, 11-19, 21-29, 34-35, 38, 41-49, 51-59, and 61-62 are presently pending and claims 1-3, 6-7, 9, 11-13, 16-17, 19, 21-23, 26-27, 29, 41-43, 46-47, 49, 51-53, 56-57, 59, and 61-62 are under consideration.

Information Disclosure Statement

The Information Disclosure Statement filed 4/18/07 has been entered and the information disclosed therein has been considered. Initialed copy of the form PTO-1449 is herein enclosed.

Specification

The specification is objected to because of the following:

The disclosure is objected to also because it contains an embedded hyperlink and/or other form or browser-executable code. Such code is present in the specification at least on page 2. Applicants are required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP ' 608.01. This objection is reiterated from the previous Office

action. While applicant amended the specification by changing <http://www.ncbi.nlm.nih.gov/entrez/> to www.ncbi.nlm.nih.gov/entrez/, the latter is still a executable code. As a matter of fact, while the examiner was drafting this paragraph, he clicked the code on this action together with the control key on the keyboard, and it led him to the website. "WWW" should also be deleted in order to make it completely inactive and inexecutable.

Appropriate correction is required.

Claim Rejections-35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3, 6-7, 9, 11-13, 16-17, 19, 21-23, 26-27, 29, 41-43, 46-47, 49, 51-53, 56-57, 59, and 61-62 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

This rejection is reiterated from the previous Office action with modification, which is necessitated by applicant's amendment.

The claims are drawn to a process, or a computer program product or recording medium for sequence display. The process comprises accepting information relating to mutations/similarities between a plurality of sequences and adding visual characteristics and displaying the sequences. Note that the displaying step is to display the original plurality of sequences and they could be the sequences without having visual characteristics added on. The homology searching process

comprises analyzing a query sequence to a sequence database, generating search conditions, analyzing the search results and generating information relating to mutations/similarities in plurality of sequences, and using the information generated and displaying the sequences. Claim 62 is drawn to a computer program product having a computer readable medium comprising computer instructions therein.

The following analysis of facts of this particular patent application follows the rationale suggested in the "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (OG Notices: 22 November 2005, available from the US PTO website at <http://www.uspto.gov/web/offices/com/sol/og/2005/week47/og200547.htm>).

The Guidelines states:

To satisfy section 101 requirements, the claim must be for a practical application of the § 101 judicial exception, which can be identified in various ways (Guidelines, p. 19):

- *The claimed invention "transforms" an article or physical object to a different state or thing.*
- *The claimed invention otherwise produces a useful, concrete and tangible result, based on the factors discussed below.*

In the instant case, at least one embodiment of the claimed invention merely manipulates sequence data without transforming an article or physical object to a different state or thing outside a computation device.

Furthermore, the invention does not produce a useful, concrete and tangible result. Specifically it does not produce a tangible result. While the claimed process comprising a displaying step, at least one embodiment is to display the original plurality of sequences do not have the visual characteristics added on. Thus, at least one embodiment of the process merely

manipulates sequence data without using or making available for use the results of the manipulation to enable its functionality and usefulness to be realized.

Additionally, claims 21-23, 26-27, 29, 41-43, 46-47, 49, 51-53, 56-57, 59, and 61-62 are drawn to "computer program product" or "recording medium." While the instant specification does not explicitly define the scope of the limitation of "computer readable medium," one skilled in the art would understand that computer readable medium includes carrier wave, which is a signal. For example, Fiekowsky et al., in US patent 6,090,555 (Date of Patent: July 18, 2000), define computer readable medium as being "a CD-ROM, floppy disk, tape, flash memory, system memory, hard drive, and a data signal embodied in a carrier wave." See column 14, claim 12. Bornstein et al., in US patent 6,1443,88 (Date of patent : Nov. 7, 2000) state, "The computer readable medium of the present invention generally includes a tape, a floppy disk, a CD ROM, a carrier wave. In a preferred embodiment, however, the computer readable medium of the present invention is a carrier wave." See column 8, lines 33-37.

Therefore, at least one embodiment of the instant claims 21-23, 26-27, 29, 41-43, 46-47, 49, 51-53, 56-57, 59, and 61-62 are drawn to carrier wave or a signal encoded thereon a computer program.

It was held by the court that claims that recite nothing but the physical characteristics of a form of energy, such as a frequency, voltage, or the strength of a magnetic field, define energy or magnetism, per se, and as such, are nonstatutory natural phenomena. O'Reilly, 56 U.S. (15 How.) at 112-14. Moreover, it does not appear that a claim reciting a signal encoded with functional descriptive material, e.g. a computer program, falls within any of the categories of

patentable subject matter set forth in § 101. The following analysis on why such a signal encoded with functional descriptive material is nonstatutory subject matter is excerpted from the US PTO's "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (OG Notices: 22 November 2005, available from the US PTO website at <http://www.uspto.gov/web/offices/com/sol/og/2005/week47/og200547.htm>):

First, a claimed signal is clearly not a "process" under § 101 because it is not a series of steps. The other three § 101 classes of machine, compositions of matter and manufactures "relate to structural entities and can be grouped as 'product' claims in order to contrast them with process claims." 1 D. Chisum, Patents §1.02 (1994). The three product classes have traditionally required physical structure or material.

"The term machine includes every mechanical device or combination of mechanical device or combination of mechanical powers and devices to perform some function and produce a certain effect or result." Corning v. Burden, 56 U.S. (15 How.) 252, 267 (1854). A modern definition of machine would no doubt include electronic devices which perform functions. Indeed, devices such as flip-flops and computers are referred to in computer science as sequential machines. A claimed signal has no physical structure, does not itself perform any useful, concrete and tangible result and, thus, does not fit within the definition of a machine.

A "composition of matter" "covers all compositions of two or more substances and includes all composite articles, whether they be results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids." Shell Development Co. v. Watson, 149 F. Supp. 279, 280, 113 USPQ 265, 266 (D.D.C. 1957), aff'd, 252 F.2d 861, 116 USPQ 428 (D.C. Cir. 1958). A claimed signal is not matter, but a form of energy, and therefore is not a composition of matter.

The Supreme Court has read the term "manufacture" in accordance with its dictionary definition to mean 'the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery.' Diamond v. Chakrabarty, 447 U.S. 303, 308, 206 USPQ 193, 196-97 (1980) (quoting American Fruit Growers, Inc. v. Brogdex Co., 283 U.S. 1, 11, 8 USPQ 131, 133 (1931), which, in turn, quotes the Century Dictionary). Other courts have applied similar definitions. See American Disappearing Bed Co. v. Arnaelsteen, 182 F. 324, 325 (9th Cir. 1910), cert. denied, 220 U.S. 622 (1911). These definitions require physical substance, which a claimed signal does not have. Congress can be presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change. Lorillard v. Pons, 434 U.S. 575, 580 (1978).

Thus, Congress must be presumed to have been aware of the interpretation of manufacture in American Fruit Growers when it passed the 1952 Patent Act.

A manufacture is also defined as the residual class of product. 1 Chisum, § 1.02[3] (citing W. Robinson, The Law of Patents for Useful Inventions 270 (1890)). A product is a tangible physical article or object, some form of matter, which a signal is not. That the other two product classes, machine and composition of matter, require physical matter is evidence that a manufacture was also intended to require physical matter. A signal, a form of energy, does not fall within either of the two definitions of manufacture. Thus, a signal does not fall within one of the four statutory classes of § 101.

[.....]

These interim guidelines propose that such signal claims are ineligible for patent protection because they do not fall within any of the four statutory classes of § 101. Public comment is sought for further evaluation of this question.

Thus, claims 21-23, 26-27, 29, 41-43, 46-47, 49, 51-53, 56-57, 59, and 61-62 are drawn to nonstatutory subject matter.

While, in the response filed 2/12/07, applicant amended claims 1-3, 6-7, 9, 11-13, 16-17, 19 to include a “displaying” step, there is no clear indication that the sequences etc. are displayed to a user. The rejections for 1-3, 6-7, 9, 11-13, 16-17, 19 may be overcome by amending the claims to display or output the specific final results to a user.

Claim Rejections-35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6-7, 9, 11-13, 16-17, 19, 21-23, 26-27, 29 are rejected under 35 U.S.C.

§ 102(b) as being anticipated by Thompson et al. (Nucleic Acids Research, Vol. 25, pages 4876-4882, 1997).

This rejection is reiterated from the previous Office action with modification, which is necessitated by applicant's amendment.

The claims are drawn to a sequence display process, or a computer program product or recording medium for the process. The sequence display process comprises accepting information relating to mutations/similarities between a plurality of sequences and adding visual characteristics and displaying the sequences. Note that the displaying step is to display the original plurality of sequences and they could be the sequences without having visual characteristics added on.

Thompson et al. disclose a sequence search and display method, referred to as CLUSTAL X. The method comprises a sequence display mechanism where visual characteristics, i.e. color, is added to the sequences where the similarities among a plurality of amino acid sequences reside after information relating to similarities among a plurality of sequences are obtained. See Fig. 1. Note that the copy of the cited reference by Thompson et al. is a black and white copy. However, a version of the reference with the original colors can be obtained online from the website with the following URL: <http://nar.oxfordjournals.org/cgi/reprint/25/24/4876>.

As to claims 2-3, 6-7, and 9, as can be seen from the color version of Fig. 1, in the alignment of a plurality of amino acid sequences, multiple different colors are used to indicate sequences of homology shared by the plurality of sequences. For example, yellow color is added to show "P." And the color is added according to degree of similarities. For example, yellow is

only used for the identical sequence, i.e. 100% homology, "P," whereas purple is used for less homologous sequences such as "D" and "E," which are not identical but both belong to acidic residue group. The colors are added using pull-down "colors" menu. See Fig. 1.

As to claims 11-13, 16-17, 19, 21-23, 26-27, 29, which are drawn to a device and computer program for the sequence display, Thompson et al. disclose all necessary systems, devices and computer software needed for CLUSTAL X. See page 4877, left column. Further, Thompson et al. state that "The CLUSTAL X code is written in ANSI C, and should be portable to any machine capable of supporting the NCBI Vibrant toolkit. CLUSTAL X is available for a number of platforms including SUN Solaris, IRIX ... The source code is provided for anyone wishing to port to any other platform supported by the Vibrant project." Thompson et al. also provide the hyperlinks for downloading the source codes. See page 4877, left column. Therefore, Thompson et al. disclose the device and computer program for the method.

Applicant's arguments filed 2/12/07 have been fully considered but they are not persuasive. Applicant argues that the amended claim 1, etc. now recites adding links between a plurality of similar sequences and relevant information and Figure 1 of Thompson fails to show links. This is not found persuasive. Absent a clear definition for the term "link" to indicate otherwise, it is interpreted as being anything that can link the sequences in any way, shape or form. Figures 1 and 2 of Thompson clearly use different colors as links for the degree of similarity/identify among the many sequences.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 41-43, 46-47, 49, 51-53, 56-57, 59, and 61-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (Genome Research, Vol. 7, pages 649-656, 1997) in view of Thompson et al. (Nucleic Acids Research, Vol. 25, pages 4876-4882, 1997) as applied to

claims 1-3, 6-7, 9, 11-13, 16-17, 19, 21-23, 26-27, 29 above.

This rejection is reiterated from the previous Office action with modification, which is necessitated by applicant's amendment.

The claims are drawn to a process or device or computer program for performing the process for homology search. The process includes analyzing a query to a database, generating search conditions,

Zhang et al. disclose a method, device and computer program for conducting nucleic acid or amino acid sequence searches, referred to as PowerBLAST. The method comprises analyzing a query sequence by identifying and filtering repetitive subsequences in the query, generating different search conditions such as BLASTN, BLASTP, BLASTX or TBLASTN with specific parameters. If the query sequence is large, it is split into overlapping pieces and the results are merged. See page 654, and Figs 5 and 6. The method also comprises analyzing the search results to generate organism specific results and more sensitive gapped alignments. See page 649, right column, last paragraph.

However, Zhang et al. do not teach displaying the search results using a method as in claim 1, i.e. a method comprising accepting information relating to mutations/similarities between a plurality of sequences and adding visual characteristics and displaying the sequences.

As applied to claims 1-3, 6-7, 9, 11-13, 16-17, 19, 21-23, 26-27, 29 above, Thompson et al. disclose a method, device and computer program for sequence display comprising accepting information relating to mutations/similarities between a plurality of sequences and adding visual characteristics and displaying the sequences. Thompson et al. design a pull-down menu for using multiple colors for the alignment display. Thompson et al. state that the coloring system used to

highlight conserved residue features in the alignment is versatile and configurable. See page 4877, left column, top paragraph.

One of ordinary skill in the art would have been motivated by Thompson et al. to modify the method disclosed by Zhang et al. to use the display system by Thompson et al. to display the sequence search results because the system of Thompson et al., in addition to its features of “easy to use, providing an integrated system for performing multiple sequence and profile alignments and analyzing the results (see Abstract),” includes the coloring system for easy recognition of different conserved residues in the aligned sequences. And the coloring system is easy to use as it contains a pull-down menu. Therefore, a homology searching method, device and computer program as claimed in the instant claims 41-43, 46-47, 49, 51-53, 56-57, 59, and 61-62 would have been obvious to one having ordinary skill in the art at the time the invention was made over the combination of Zhang et al. and Thompson et al.

Applicant’s arguments filed 2/12/07 have been fully considered but they are not persuasive. Applicant’s argument is essentially the same as that presented for the rejection under 35 USC 102 above, i.e. either Zhang et al. nor Thompson teaches adding links between the plurality of sequences. This is not found persuasive for the same reasons set forth above.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL.

Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. §1.136 (a). A shortened statutory period for response to this final action is set to expire three months from

the date of this action. In the event a first response is filed within two months of the mailing date of this final action and the advisory action is not mailed until after the end of the three-month shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136 (a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than six months from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Shubo (Joe) Zhou/

SHUBO (JOE) ZHOU, PH.D.

PRIMARY EXAMINER